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09/961,100	09/24/2001	Lucie Elise Letourneau	112785.7800	5991

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	S

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/961,100	Applicant(s) Letourneau et al.
Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Jan 3, 2003
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- 4)  Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) 21 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-20 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Restriction/Election***

Applicants' election without traverse of the Group I (claims 1-20 ) invention in Paper No. 4 filed 1/03/2003 is acknowledged. Claim 21 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention directed to a method for preventing or treating vaginal dryness, there being no allowable generic or linking claim.

Claims 1-20 are under examination in the instant office action.

### ***Claim Objections***

Claim 15 is objected to because of the following informalities:

The Latin name “*Sepia officinalis*” appears to contain a typing error according to the disclosure of the IDS references {Clarke [IDS-7] and/or Guermonprez et al. [IDS-8]}.

Appropriate correction is required.

There is a typing error such as coma before “and” in the last line of the claim.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and has an improper Markush group because it is uncertain what are the members of the group as claimed. Are they fatty acids and dilutions? Are they fatty acids,

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dilutions of plants and animal extracts? It is suggested to indicate that animal extracts are also present in homeopathic dilutions, if that is intended, to avoid confusion. For example: "selected from the group consisting of A, B and C". MPEP 2173.05 (h).

With respect to claims 1, 14, 16 and 17 it is noted that although the general meaning of "homeopathic" amount or dilution encompasses the use of low concentrations of material of interest, the amounts that are claimed are uncertain in the absence of definitions or examples to rely upon in the as-filed specification. For example: the amount of starting materials for making "homeopathic" preparations is unknown as disclosed (page 8, last par.) and, thus, the final concentration in the "homeopathic dilutions" are unknown.

Claim 2 recites the limitation "a mixture of fatty acids" in a lubricant composition. There is insufficient antecedent basis for this limitation in the claim 1 because it is uncertain whether the claimed mixture refers to "fatty acids" or to "homeopathic dilutions" or to both. It is also confusing whether ingredient such as "fatty acids" of claim 1 might refer to one type of fatty acid.

Claim 5 is rendered indefinite by the phrase "comprises" as related to the composition wherein variety of component is substantially limited by the virtue of the language "consisting essentially of" (claim 2). It is suggested to write, for example: "wherein said fatty acids derived from hemp oil" or "wherein said fatty acids are hemp seed oil fatty acids", if that is intended. The same rejection is applied to claims 6 and 7 with respect to the phrase "comprising". No

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suggestion is made herein with respect to claims 6 and 7 because components and amounts are uncertain as related to the lubricant compositions of claims 6 and 7 as intended by applicants.

Claim 10 is rendered indefinite by the phrase "further comprises" as related to the composition wherein variety of component is substantially limited by the virtue of the language "consisting essentially of" (see claim 2) or wherein "homeopathic dilution" appears to be excluded (see claims 2 and 1).

Claims 11, 19 and 20 are rendered indefinite by the phrase "it" or "it forms" because it is uncertain what is intended as "it". Is "it" a composition as a whole? Is "it" a composition ingredient?

Claim 13 is indefinite as related to ingredients/components. The intended use as claimed does not indicate ingredients/components which would make the claimed composition either "vaginal moisturizer" or "personal lubricant".

Claims 14-19 are indefinite as related to the phrases "the lubricant composition" (claims 14-17 and 19) or "the genital lubricant composition" (claim 18). It is uncertain whether this inconsistency is a typing error. It is uncertain whether there are some unidentified components which are intended to be included or excluded from the composition.

The use of parentheses in claim 15 is indefinite because it is unclear if what is stated in parentheses is a further limitation or simply alternative meaning. This is particularly uncertain as related to animal extract since there is only one animal such as cuttlefish *Sepia* but not several animals in the Markush group. Thus, the claimed Markush group is improper.

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Claim 18 is rendered indefinite by the phrase "further comprising" as related to the composition wherein variety of component is substantially limited by the virtue of the language "consisting essentially of" (see claim 14) or wherein ingredient intended as "fatty acids" appears to be excluded (see claims 2 and 1).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US

6,063,369 [IDS-3].

Claims are directed to a lubricant composition comprising fatty acids derived from hemp seed oil, homeopathic dilutions of plant extracts and physiologically acceptable carrier. Some claims are further drawn to the use of fatty acids such as linoleic and linolenic fatty acids in the ratio of about 1 to 3 in the lubricant composition. Some claims are further drawn to the concentration of hemp seed oil fatty acids such as about 0.01-3% vol/vol or 0.05 to 0.5% in the lubricant composition. Some claims are further drawn to the concentration of plant homeopathic dilutions such as about 1% vol/vol in the lubricant composition. Some claims are further drawn to the use of physiologically acceptable carrier which comprises water, thickening agent and

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lubricating agent in the lubricant composition and to the forms of the composition such as lotion, gel or cream.

US 6,063,369 [IDS-3] discloses a lubricant composition (table 7) comprising fatty acids derived from hemp seed oil, homeopathic dilutions of plant extracts or "botanicals" and physiologically acceptable carrier. The cited patent teaches that hemp seed oil of the lubricant composition comprises linoleic and linolenic fatty acids in the ratio of about 1 to 3 (col. 8, lines 12-13 and col. 1, lines 50-61). The lubricant composition of the cited patent comprises hemp seed oil in amounts 0.01-10% and botanicals in amounts of 0.5-20%, for example: see table 6 or 7. The physiologically acceptable carrier of the lubricant compositions comprises water, thickening agent and lubricating agent (table 6 or table 7). The lubricant composition with hemp seed oil forms lotion, gel or cream. The lubricant composition with hemp seed oil of the cited patent is said to treat skin dryness (col. 8, line 10).

The cited patent US 6,063,369 [IDS-3] is considered to anticipate the claimed invention because the composition of the cited patent comprises identical components at identical concentration as required for the presently claimed composition. The fatty acid composition of the hemp seed oil is identical to that is claimed whether in a composition with ingredients including botanicals (table 7) or in a composition "consisting essentially" of hemp seed oil fatty acids (table 6). The "botanicals" of the lubricant composition (table 7) are considered to be "homeopathic dilutions" of plant extracts as required for the claimed composition because they are present in the same amount in the whole composition as claimed. With respect to limitation

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“homeopathic” dilution (low concentration of plant material) it is uncertain as claimed and as disclosed what are the amounts of starting plant materials to obtain “homeopathic” dilutions/preparations, and, thus, the amounts of “botanicals” are considered to be substantially the same as intended for the presently claimed composition in order to provide lubricant composition effective for treating dryness. With respect to claims 1, 14 and 16-19 the table 7 composition is considered to anticipate the claimed invention because it is uncertain what ingredients are included or excluded due to confusion in the use of phrases “comprising”, “consists essentially of” and “further comprising” in the present claims. Although the intended use of the presently claimed composition is a genital lubricant, the claimed ingredients and amounts are the same as the ingredients and amounts in the compositions of the cited patent. Thus, the compositions of the cited patent are effective to the same extent as the presently claimed composition, particularly in view that the skin cream/lotion composition of the cited patent is effective in treating dryness due to incorporation of hemp seed oil and/or botanicals as taught by the cited patent.

Therefore, the cited patent US 6,063,369 is considered to anticipate the claimed invention.

Claims 1, 14, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke [IDS-7] in the light of evidence by Guermonprez et al. [IDS-8].

Claims are directed to a genital lubricant composition consisting essentially of homeopathic dilutions of plant or animal extract in combination with a physiologically

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acceptable carrier. Some claims are further drawn to use of homeopathic dilutions/preparations of plant or animal extracts derived from the species of *Caladium seguinum*, *Sepia officinalis*, *Lycopodium clavatum* or *Onosmodium virginianum*. Some claims are further drawn to the use of effective amount of homeopathic dilutions suitable for genital application and for treating problems associated with sexual intercourse.

The cited reference by Clarke [IDS-7] teaches compositions consisting essentially of homeopathic dilutions of plant or animal extract in combination with a physiologically acceptable carrier such as tinctures derived from plant and animal species of *Caladium seguinum*, *Sepia officinalis*, *Lycopodium clavatum* and *Onosmodium virginianum* as preparations effective for treating vaginal dryness and for treating problems associated with sexual intercourse, for example: see page 329, par. 1-2 for a tincture of spores of *Lycopodium clavatum*; page 332 and page 334 for a tincture of plant *Caladium seguinum*; page 658 and page 662 for a tincture of plant *Onosmodium virginianum*; pages 1158 -1159 for a tincture of fish *Sepia officinalis*.

The reference by Guermonprez et al. [IDS-8] is relied upon to demonstrate that the preparations derived from plant and animal species of *Caladium seguinum*, *Sepia officinalis*, *Lycopodium clavatum* and *Onosmodium virginianum* which are taught by Clarke [IDS-7] are inherently the “homeopathic” medicinal preparations (title page and pages 145, 457, 554, 677).

The cited reference by Clarke [IDS-7] is considered to anticipate the presently claimed invention because the cited tinctures are the compositions consisting essentially of homeopathic preparations derived from plant and animal species of *Caladium seguinum*, *Sepia officinalis*,

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*Lycopodium clavatum* and *Onosmodium virginianum* in combination with a carrier. Although the cited tinctures are not disclosed as being in a form of vaginal lubricants, the contents of the cited compositions and of the presently claimed composition are identical. Moreover, the cited tinctures are taught to be effective for treating of vaginal dryness and for treating problems associated with sexual intercourse as encompassed by the presently claimed invention. Thus, the effective amounts of the cited tinctures are identical to the claimed effective amounts within the meaning of the present application and claims.

Therefore, the cited reference by Clarke [IDS-7] is considered to anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,063,369 [IDS-3] taken with US 6,267,985 [A].

Claims are directed to a lubricant composition comprising fatty acids derived from hemp seed oil, homeopathic dilutions of plant or animal extracts and physiologically acceptable carrier. Some claims are further drawn to the use of fatty acids such as linoleic and linolenic fatty acids

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in the ratio of about 1 to 3 in the lubricant composition. Some claims are further drawn to concentration of hemp seed oil fatty acids such as about 0.01-3% vol/vol or 0.05 to 0.5% in the lubricant composition. Some claims are further drawn to concentration of plant homeopathic dilution such as about 1% vol/vol in the lubricant composition. Some claims are further drawn to the use of physiologically acceptable carrier which comprises water, thickening agent and lubricating agent in the lubricant composition, to the form of the composition such as lotion, gel or cream.

The cited patent US 6,063,369 [IDS-3] is relied upon for the disclosure of a lubricant composition effective for treating skin dryness which comprises hemp seed oil fatty acids, homeopathic dilutions of plant extracts and physiologically acceptable carrier as explained above. It is lacking particular disclosure related the use of animal extracts in the lubricant compositions and as related to the use of hemp seed oil in composition suitable for vaginal applications.

However, US 6,267,985 [A] discloses pharmaceutical compositions (abstract) suitable for both topical and vaginal applications (col. 36, lines 26-27) wherein the composition comprises triglycerides and carrier, wherein suitable triglycerides include hemp seed oil (col. 5, line 57) and wherein the composition comprises other preparations derived from plant extracts (table 1 or col. 35, line 13) and animal extracts (col. 6, line 15 or col. 35, lines 13-15) as the fatty acid or triglyceride ingredient or as the therapeutic agent.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain the topical lubricant composition of US 6,063,369 [IDS-3] in a form suitable for vaginal application as intended for the presently claimed invention with a reasonable expectation of success because the cited prior art teaches hemp seed oil fatty acid or triglyceride containing pharmaceutical compositions as suitable for both topical and vaginal applications {US 6,267,985 [A] and US 6,063,369 [IDS-3]}. One of ordinary skill in the art would have been motivated to use hemp seed oil in pharmaceutical compositions suitable for topical or vaginal applications because hemp seed oil as well as other plant essential oils is known for treating dryness and/or delivering therapeutic agents {US 6,267,985 [A] and US 6,063,369 [IDS-3]}. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,063,369 [IDS-3] taken with US 6,267,985 [A] as applied to claims 1-14 and 16-20 above, and further in view of Clarke [IDS-7] and Guermonprez et al. [IDS-8].

Claims 1-14 and 16-20 as explained above. Claim 15 is further drawn to the use of homeopathic dilutions/preparations of plant or animal extracts derived from the species of

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*Caladium seguinum, Sepia officinalis, Lycopodium clavatum or Onosmodium virginianum* in the lubricant composition.

The cited US 6,063,369 [IDS-3] and US 6,267,985 [A] are relied upon as explained above for the disclosure of pharmaceutical lubricant compositions suitable for topical and vaginal applications comprising hemp seed oil, therapeutic or homeopathic agents derived from plant or animal extracts and carrier. But the cited patents US 6,063,369 [IDS-3] and US 6,267,985 [A] are missing particular disclosure related to the source of plant and/or animal extracts such as species of *Caladium seguinum, Sepia officinalis, Lycopodium clavatum* and *Onosmodium virginianum*.

The cited reference by Clarke [IDS-7] is relied upon for the teaching of plant and animal species of *Caladium seguinum, Sepia officinalis, Lycopodium clavatum* and *Onosmodium virginianum* as the valuable source of therapeutically effective preparations or homeopathic preparations intended for treating dryness of skin and/or vagina and for treating problems associated with sexual intercourse (pages 329, 334, 662 and 1158). In addition, the reference by Guermonprez et al. [IDS-8] is relied upon to demonstrate that the preparations derived from plant and animal species of *Caladium seguinum, Sepia officinalis, Lycopodium clavatum* and *Onosmodium virginianum* are considered to be "homeopathic" preparations (title page and pages 145, 457, 554, 677).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use preparations derived from plant and animal species of *Caladium seguinum, Sepia officinalis, Lycopodium clavatum* and *Onosmodium virginianum* in

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the lubricant compositions with a reasonable expectation of success in both topical and/or vaginal applications because prior art teaches these materials as effective for therapeutic or homeopathic clinical applications intended for treating dryness of skin and/or vagina and for treating problems associated with sexual intercourse. Thus, one of ordinary skill in the art would have been motivated to incorporate the presently claimed plant and/or animal derived materials into the hemp seed oil containing pharmaceutical compositions of US 6,063,369 [IDS-3] and/or US 6,267,985 [A] suitable for topical or vaginal applications for the expected benefits in obtaining compositions intended for treating dryness of skin and/or vagina and for treating problems associated with sexual intercourse. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

***Information Disclosure Statement***

In response to the applicants' remarks [Paper No. 4] it is noted that the document #12 containing 10 pages [IDS filed 9/24/2001, part of papers No. 1] was/is not considered on PTO Form 1449 because it is a reference to a particular website which does not and can not provide full listing of products intended by applicants due to the fact that website information is a subject to changes. It is uncertain how many and what products might have been within the "shopinprivate.com" website during 2001. Moreover, there are at least two particular dates when information related to some products has been retrieved, thus, adding to the confusion what

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products from the website might be included or excluded. Furthermore, the products which are listed within the document #12 are uncertain with respect to their contents. It is uncertain whether they do or do not comprise hemp oil and other materials as the presently claimed product. It is suggested to provide a separate reference on PTO Form-1449 for each of 10 webpages with the precise date of retrieval of the information related to the webpage or product as intended together with a concise explanation in the accompanying papers of their relevance to the presently claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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VERA AFREMOVA

April 1, 2003

PATENT EXAMINER

